

**Remarks**

Reconsideration and withdrawal of the objection to the specification and rejections of the claims, in view of the remarks and amendments herein, is respectfully requested. Claims 28-29, 32 and 34-36 are amended, and claims 37-42 are added. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims pending prior to amendment, which claims are in a continuation of the above-identified application. Claims 1-42 are pending.

In response to the finality of the Restriction Requirement, Applicant reserves the right to petition the Commissioner to review the Restriction Requirement.

The amendment to the Abstract overcomes the objection thereto at page 3 of the Office Action.

The Examiner rejected claims 28-29, 32 and 34-36 under 35 U.S.C. § 112, second paragraph, as being indefinite. The amendments to claims 28-29, to spell out transforming growth factor beta-1, insulin-like growth factor binding protein-2, insulin-like growth factor binding protein-3, interleukin-6 and interleukin-6 soluble receptor, obviate the § 112(2) rejections.

The Examiner rejected claims 28-36 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for prostate cancer and cancer originating from the prostate, allegedly does not reasonably provide enablement for other disease. The Examiner also rejected claims 28-36 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for humans, purportedly does not enable mammals other than humans. The amendments to claims 28-29 and 34-36, to clarify that the sample is from a human patient with clinically localized prostate cancer and that the apparatus and methods provide the risk of prostate cancer progression or non-prostate confined disease in a prostate cancer patient, moot those rejections.

The Examiner further rejected claims 28-33 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for each recited protein individually, allegedly does not reasonably provide enablement for combinations of the proteins. This rejection is respectfully traversed.

To support the conclusion that “results of combinations are unpredictable in that growth factors can augment or regulate each other in the form of interactions that can be cooperative or uncooperative” (page 10 of the Office Action), the Examiner points to the abstract for Antonello (Ph.D. Thesis, Temple University, 1996), Lamy et al. (Disease of the Nervous System, 32:17 (1971)), Yip et al. (Postgrad. Medical J., 66:367 (1990)), and Tirone et al. (J. Biol. Chem., 272:4787 (1997)).

It is unclear to Applicant’s Representatives how the joint action of two or more drugs administered in combination (Antenello), interactions of salicylates with other drugs (Lamy et al. and Yip et al.), the impact of salicylates on certain test values (Lamy et al.), drug interactions with foods (Lamy et al.), or the regulation of hyaluronan synthesis by follicle-stimulating hormone or epidermal growth factor and soluble oocyte factor or TGF- $\beta$ 1 in mouse cumulus cells (Tirone et al.), supports the Examiner’s position.

Applicant’s invention is an apparatus and methods for predicting outcomes in prostate cancer patients subjected to local therapy for prostate cancer, where the prediction is based on the level or amount of certain proteins in a physiological fluid sample from a prostate cancer patient. In particular, it is disclosed that the level or amount of particular proteins in a physiological fluid sample from prostate cancer patients was determined, and a correlation was found between the level or amount of certain proteins and patient outcome (see Examples 1-4).

It is also disclosed that those proteins can be employed with other factors or with each other, in the apparatus and methods of the invention (page 4, lines 6-12, page 7, lines 20-25, and page 8, lines 23-25). Moreover, it well-known that the use of multiple factors can improve predictive methods (see, e.g., the abstract for Bostwick et al., Semin. Urol. Oncol., 17:222 (1999)). Thus, Applicant’s specification is fully enabling.

Accordingly, withdrawal of the § 112 rejections is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

KEVIN M. SLAWIN ET AL.

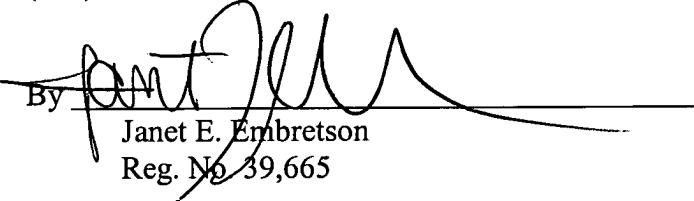
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date

January 3, 2006

By

  
Janet E. Embretson  
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3 day of January, 2006.

Name

John D. Grotter-Watshall

Signature

